

The effect of specific surface area of chitin-metal silicate coprocessed excipient on the chemical decomposition of cefotaxime sodium

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Abstract: Chitin-metal silicates are multifunctional excipients used in tablets. Previously, a correlation between the surface acidity of chitin-calcium and chitin-magnesium silicate and the chemical decomposition of cefotaxime sodium was found but not with chitin-aluminum silicate. This lack of correlation could be due to the catalytic effect of silica alumina or the difference in surface area of the excipients. The objective of this study was to investigate the effect of the specific surface area of the excipient on the chemical decomposition of cefotaxime sodium in the solid state. Chitin was purified and coprocessed with different metal silicates to prepare the excipients. The specific surface area was determined using gas adsorption. The chemical decomposition was studied at constant temperature and relative humidity. Also, the degradation in solution was studied. A correlation was found between the degradation rate constant and the surface area of chitin-aluminum and chitin-calcium silicate but not with chitin-magnesium silicate. This was due to the small average pore diameter of this excipient. Also, the degradation in solution was slower than in solid state. In conclusion, the stability of cefotaxime sodium was dependent on the surface area of the excipient in contact with the drug.